



American Dietetic Association

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October 9, 2003

Food and Drug Administration
Department of Health and Human Services
Attention: HFA-305
Docket #: 03N-0076
5630 Fishers Lane
Rockville, MD 20852

Dear Sir or Madam:

The American Dietetic Association (ADA) represents nearly 70,000 food and nutrition professionals serving the public through the promotion of optimal nutrition, health and well being. ADA appreciates this opportunity to respond to the Food and Drug Administration's (FDA) advanced notice of proposed rulemaking (ANPR) published in the July 11, 2003 *Federal Register* on trans fatty acids in nutrition labeling. Included with these comments are copies of previously submitted comments by ADA in April 2000 and January 2001.

General Comments

ADA commends FDA's decision to require nutrition labels to include the amounts of trans fatty acids contained in packaged foods. Providing this information will help millions of people who wish to reduce overall consumption of foods that may increase their risk of coronary heart disease (CHD), make healthy food choices and lower their cholesterol. As FDA is aware, clinical studies demonstrate that trans fat can raise blood cholesterol and presents relative risks for CHD that are similar to those for saturated fat (*Institute of Medicine, 2002*).

ADA encourages FDA to accompany the new trans fatty acid labeling requirements with public and private consumer education efforts. Such efforts are critical to increase public awareness and understanding of trans fat, as well as to help prevent consumer confusion. Continued consumer nutrition education efforts are needed to accompany our evolving knowledge of science, as well as

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changes in the marketplace and on food labels. As new information emerges about the physiologic function of various fatty acids, even sophisticated consumers are likely to be confused in the absence of clear consumer messages and food labels. Education can and should be a shared responsibility among the public and private sectors and FDA should encourage individuals and organizations to participate in these efforts.

Amendment of 1999 FDA proposed rule to require *trans* fat declaration on a separate line without a percent Daily Value

ADA supports FDA's recent action to require that *trans* fat be declared in the nutrition label of conventional foods and dietary supplements on a separate line immediately under saturated fat, but without a percent Daily Value (% DV.) We believe this new labeling information on *trans* fat will provide consumers with information they need to help them make healthy food choices in the context of their total daily diet.

ADA recognizes the challenge FDA faces in determining a % DV for *trans* fat in foods. To date, no scientific body has recommended a DV for *trans* fat, which would be used to calculate a % DV. The Institute of Medicine's September 2002 Dietary Reference Intakes (DRI) for Macronutrients report recommended that "*trans* fatty acid consumption be as low as possible while consuming a nutritionally adequate diet." The DRI did not establish a tolerable upper intake level. In addition, data on the current amount of *trans* fats in many food items is limited (U.S. Department of Agriculture, 2003).

As stated in our previous comments on *trans* fat labeling, ADA discourages both the combination of saturated fat and *trans* fat in one line in the nutrient declaration and the use of a combined %DV for saturated and *trans* fat. All numbers on the current food label are based on specific chemical definitions for each nutrient. Placing *trans* fat within the category of saturated fat would be scientifically inaccurate, since *trans* fat, as it is derived from unsaturated fat, has a different chemical structure from saturated fat but functions differently metabolically than an unsaturated fat. Combining the two types of fat into a common category suggests that *trans* fat is a form of saturated fat. That is misleading and potentially sets a precedent for changing interpretation of the entire food label.

FDA request for consumer research data

As stated in the July 11, 2003 ANPR, FDA has a mandate to provide nutrition information on food labels to assist consumers in maintaining healthy dietary practices. In response to FDA's request for consumer research data to help evaluate footnotes or qualifying criteria for *trans* fat in various nutrient content claims (saturated fat, *trans* fat, cholesterol, lean and extra lean) and health claims, we direct attention to recent findings from research conducted by the

International Food Information Council (IFIC) Foundation (IFIC Foundation 2002) and submitted to FDA on consumer use of the food label, with specific reference to *trans* fat declaration and the previously proposed (November 2002) *trans* fat Daily Value footnote.

A summary of the research conducted indicates that when consumers use the current Nutrition Facts panel to ascertain a product's overall healthfulness, they tend to rely on a variety of components such as calories, total fat, saturated fat and sodium. However, when consumers use the proposed Nutrition Facts panel containing a *trans* fat footnote, they place disproportionate weight on the *trans* fat nutrition information, discounting other important nutrient content information.

Consumers repeatedly identified food products without *trans* fat as the healthier choice when they were given nutrition label information along with a *trans* fat footnote. For example, butter was overwhelmingly chosen over margarine as the preferred food despite the fact that the combined total of saturated and *trans* fat (7 grams saturated fat and 0 grams *trans* fat) for butter as listed on the label was almost twice that of margarine (2 grams saturated fat and 2 grams of *trans* fat). The report further states that when consumers were asked why they chose the *trans* fat-free product as the healthier choice when the footnote was present, they almost always cited the *trans* fat content, overlooking information about calories, total fat, sodium, saturated fat, cholesterol or other nutrient or food components. Consumers indicated that the footnote conveyed to them that *trans* fat was worse than saturated fat.

The ANPR assumes that a footnote, one of several identified in the FDA notice, is the appropriate way to proceed. Given the potential influence of footnotes on consumer's dietary choices, currently demonstrated as a negative response to food choices for health, ADA strongly recommends that FDA gather additional information on their potential use in nutrition labeling and their effect on consumer choices. First, ADA recommends that FDA determine whether footnotes are meaningful to consumers and be constructed to not direct consumers to unintended or negative dietary choices. The previously proposed footnote statement "Intake of *trans* fat should be as low as possible" clearly led consumers to avoid *trans* fat without attention to saturated fat or other nutrients or food components. Any alternative footnote or label statement warrants further testing to ensure that consumers are not driven toward products that are devoid of *trans* fat, regardless of the level of saturated fat, total fat or cholesterol.

An upcoming Food and Nutrition Board (FNB) report is expected to address the issue of the use of dietary reference intakes (DRI) in nutrition labeling. This report will elaborate on principles for developing label reference values or other information for nutrients described in DRI reports. FDA may be able to draw from the FNB report and other consumer research data before proposing footnotes or qualifying criteria for nutrient content claims related to *trans* fat. Likewise effect of criteria for *trans* fat, saturated fat and dietary cholesterol in

health claims should be carefully considered and tested prior to allowing claims on foods.

Finally, and perhaps most importantly, ADA strongly advocates continued, intensified and pilot-tested consumer education about how to read and use food labels and about saturated fat, *trans* fats and cholesterol. Dietetics professionals are uniquely trained and qualified to facilitate this process and help consumers translate emerging scientific evidence into practical dietary behaviors. We applaud and appreciate the agency's efforts in this important public health arena.

Sincerely,



Marianne Smith Edge, MS, RD, FADA
President

Attachments: ADA Comments from April 2000 and January 2001
http://www.eatright.org/Member/PolicyInitiatives/83_lg042500.cfm
http://www.eatright.org/Member/PolicyInitiatives/83_transfats.cfm

References:

Institute of Medicine/National Academy of Sciences, *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids (Macronutrients)*. National Academy Press, Washington, DC, pp. S1-S17, 8-1 to 8-97, and 11-1 to 11-48.

U.S. Department of Agriculture, Center for Nutrition Policy and Promotion, *Notice of Availability of Proposed Food Guide Pyramid Daily Food Intake Patterns and Technical Support Data and Announcement of Public Comment Period*, Federal Register, Vol. 68, No. 176, September 11, 2003.

International Food Information Council Foundation, *Impact of trans fat label information on consumer food choices*. Study conducted January 10-24, 2003. Washington, DC: IFIC Foundation, 2003. Accessed at <http://www.ific.org/research/transres.cfm>.



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FDA Food Labeling Proposal on Trans Fatty Acids April 25, 2000

April 25, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Comments of the American Dietetic Association on the Food and Drug Administration's Proposed Rule on Food Labeling: Trans Fatty Acids, Nutrition Labeling, Nutrient Content Claims, and Health Claims

RE: Docket No. 94P-0036

The American Dietetic Association (ADA) represents nearly 70,000 food and nutrition professionals who serve the public by promoting good health through diet and physical activity. The ADA appreciates this opportunity to submit comments in response to the Food and Drug Administration's (FDA) proposed rulemaking on the labeling of trans fats. ADA commends FDA for their continued efforts to help consumers eat well and achieve their dietary goals.

General Comments

The effects of saturated fat on total and low-density lipoprotein (LDL) cholesterol are well established and dietary recommendations, including the *Dietary Guidelines for Americans*, suggest reducing intakes of foods high in saturated fat. Clinical studies demonstrate that partially hydrogenated unsaturated fat (trans fat) also raises blood cholesterol and presents relative risks for coronary heart disease (CHD) that are similar to those for saturated fat.

In light of this evidence, ADA supports FDA's proposal to amend its food labeling regulations to include information about trans fat on the labels of foods, and dietary supplements. Label information about a product's trans fat content will help consumers who wish to reduce overall consumption of foods that may increase their risk of CHD. ADA believes the addition of label information about trans fat content will allow consumers to choose more healthful diets and to place individual food selections within the context of their total diet.

The following comments will address two main issues of FDA's proposal: 1.) the use of the term "trans fat" in nutrient content claims, and 2.) format for the identification of trans fat content in nutrition labeling.

Use of "trans fat free" as a content claim

The FDA is proposing that, similar to claims allowed for "saturated fat free" or "cholesterol free," food marketers are permitted to identify products for consumers that contain less than 0.5 mg per reference amount per labeled serving of trans fats. ADA agrees with this proposal and notes that in response to growing consumer awareness about the negative health effects of trans fats, the claim "trans fat free" is already being used on some food products.

FDA is also proposing that wherever saturated fat limits are placed on nutrient content claims, health claims, disclosure or disqualifying levels, that the limits for trans fatty acids also be limited. Again, ADA agrees with this proposal.

Identification of trans fat content in food labeling

ADA recognizes the general challenge of incorporating new information in the Nutrition Facts box, and especially the particular challenges of the proposed label for trans fat. The agency is proposing to combine saturated fat and trans fat into one category, with an absolute number of grams and as a % Daily Value under the existing category labeled "saturated fat." FDA is also proposing the use of an asterisk to refer the consumer to a footnote reading "contains X grams of trans fat." The agency asserts that combining saturated fat and trans fat into one numeric value is the most useful approach to prevent consumers from being misled about the impact of a food containing trans fat on the risk of CHD.

Trans fat is unsaturated fat that differs in chemical structure from saturated fat and therefore does not meet the scientific definition of saturated fat. For this reason, ADA can not support this aspect of the proposed regulation. FDA's proposal to combine trans and saturated fat into one category suggests to consumers that trans fat is a saturated fat. All numbers on the current food label are based on specific chemical definitions for each nutrient. Placing trans fat within the category of saturated fat is scientifically inaccurate and could potentially mislead consumers.

ADA recognizes that trans fat demonstrates physiological effects similar to saturated fat, but further research may elucidate new properties or biological effects of either fat that would warrant distinguishing between the two. To combine trans fats and saturated fats under the title of saturated fats based on a known physiological effect sets a precedent for change for the entire food label.

Further, separate footnotes are often overlooked by consumers. Consumers may not become aware of new and important label information declared in a footnote that is separate from other information about a product's nutrient content. ADA is concerned that if FDA begins to mandate the placement of nutrient content information in locations other than the current nutrient list, then consumers may become increasingly confused about where on the food label they will find the information they need.

ADA recommends that the Agency instead require one line labeled as "saturated fat X grams" and "trans fat X grams" with a corresponding % DV. This proposal keeps information about 'heart unhealthy' fats together on the same line, maintains the integrity of each as different fats. ADA would also support the Agency decision to create a separate line for trans fat under saturated fat. ADA recognizes the tremendous economic burdens associated with adding a new line to the Nutrition Facts box.

Strong Need for Consumer Education

ADA members strongly recommend that label changes be accompanied by public and private consumer education efforts. These efforts are critical to increase public awareness and understanding of trans fat, among other things related to nutrition and health. Some individuals, including some ADA members, have expressed concern that the addition of another type of fat to the existing food label might detract from the important message to limit saturated fat intake. ADA believes these concerns support the strong need for continued consumer education efforts about both saturated and trans fat. ADA members recognize that combining the two "heart unhealthy" fats would simplify the atherosclerotic fat message for consumers. However, because the food label is intended as a consumer education tool, consumers expect that information in the Nutrition Facts box is scientifically accurate. The addition of trans fat to the label should receive label placement consistent with other nutrients for a food product.

Food processors, manufacturers, and food service providers should be encouraged to substitute alternate non-atherogenic fats whenever possible. The estimated current population intake of trans fat averages approximately 1% of total daily energy intake. Key sources include fried foods, hydrogenated shortening and certain margarines or products made from these fats. Because cardiovascular disease continues to be the leading cause of death in this country, educational efforts regarding unsaturated, non-trans options and their appropriate use should be directed to industry, as well as to consumers in order to maximize potential health benefits.

Finally, FDA should continue to monitor the amount of trans fat in the marketplace following the implementation of trans fat labeling. Consumer education is also recommended to evaluate whether the addition of trans fat to product labels is useful to consumers and whether this information affects food purchase decisions.

Concluding Remarks


Overall, ADA supports this proposed measure to provide consumers with better information with which to make informed dietary choices. Effects of trans fat on CHD are well established in the scientific literature and consumers should have the option to select foods based on nutrition content, including the amount of trans fat that may or may not be present in a food or dietary supplement. Transparency and accuracy based on credible scientific information must remain a priority if food labels are to continue to provide consumers and nutrition professionals with the necessary tools to work towards meeting dietary goals. For this reason, ADA urges the Agency to consider separate disclosure of a product's content of trans and saturated fat.

Continued consumer nutrition education efforts must also accompany our evolving knowledge of science as well as changes in the marketplace and food labels. As new information continues to emerge about the physiologic functions of various fatty acids, even sophisticated consumers are likely to grow increasingly confused in the absence of clear consumer messages and food labels. Education can and should be a shared responsibility among both the public and private sectors and FDA should encourage individuals and organizations to participate in these efforts.

ADA members remain committed to accomplishing these objectives and are poised to assist FDA in this and other important efforts to improve consumer health and nutrition.

Sincerely,

Ann Gallagher, RD, LD, CD
President

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FDA Food Labeling Proposal on Trans Fatty Acids Nutrition Labeling, Nutrient Content Claims, and Health Claims, Jan. 19, 2001

January 19, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Comments of the American Dietetic Association on the Food Drug Administration's Proposed Rule on Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, Health Claims

RE: Docket No. 94P-0036

The American Dietetic Association (ADA) represents nearly 70,000 food and nutrition professionals who serve the public by promoting good health through diet and physical activity. The ADA appreciates this additional opportunity to submit comments in response to the Food and Drug Administration's (FDA) proposed rulemaking on the labeling of trans fatty acids. These comments address specifically the agency's request for guidance on the appropriate labeling of foods that display nutrient content claims. ADA commends FDA for the continuing efforts to help consumers understand the information provided on nutrition labels. This information is relied upon by many Americans who use the food label as a convenient reference when making food choices.

General Comments

The effects of saturated fat on total and low-density lipoprotein (LDL) cholesterol are well established and dietary recommendations, including the *Dietary Guidelines for Americans*, suggest reducing intakes of foods high in saturated fat. Clinical studies demonstrate that partially hydrogenated unsaturated fat (trans fat) also raises blood cholesterol and presents relative risks for coronary heart disease (CHD) that are similar to those for saturated fat.

In light of this evidence, ADA reaffirms its support of FDA's proposal to amend food labeling regulations to include information about trans fat on the labels for foods and dietary supplements. Label information about a product's trans fat content will help consumers who wish to reduce overall consumption of fat that may increase their risk of CHD. ADA believes the addition of label

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information about trans fat content will allow consumers to choose more healthful diets and help them to place individual food selections within the context of their total diet.

However, ADA believes the best scientific evidence suggests that consumers should focus first on total fat and saturated fat. And, because dietary intake of saturated fat is significantly higher than intake levels of trans fat, saturated fat presents a greater health risk to most Americans.

In the December 5, 2000 *Federal Register*, FDA requested additional advice in determining legal requirements for nutrient content claims on products that contain reduced levels of trans fat and/or saturated fat.

Claims for "low saturated fat" and "reduced saturated fat"

ADA notes that section 403(r)(2)(A)(vi) of the Food, Drug and Cosmetic Act prohibits a claim if it is misleading in light of the level of another nutrient in the food. For this reason, "low saturated fat" or "reduced saturated fat" claim may be misleading if the same food or dietary supplement also contains measurable amounts of trans fatty acids. Consumers who select certain foods because they contain "low" or "reduced" levels of saturated fat are likely to assume the product does not contain other components that may adversely affect serum cholesterol levels.

ADA recommends that products labeled "low saturated fat" contain 1 gram or less of saturated fat and 0.5 gram of trans fat per reference amount and more than 15 percent of total calories from saturated and trans fat combined. ADA also recommends that products labeled "reduced saturated fat" should require a 25 percent minimum reduction in saturated fat and a total combined reduction of at least 25 percent of saturated fat and trans fat. Products that reduce both saturated and trans fat by 25% should be permitted to display a combined claim, "reduced saturated and trans fat."

Claims for "low trans fat" and "reduced trans fat"

The November 17, 1999 *Federal Register* states that FDA "considered, but rejected, proposing definitions for "low" and "reduced" trans fat. Because the claim "low" generally relates to the total amount of the nutrient recommended for daily consumption, and because there is no quantitative recommendation for daily intake of trans fat, ADA agrees with the agency's conclusion that the "low trans fat" cannot be adequately defined.

However, ADA recognizes that the food industry may wish to identify products formulated to contain a reduced level of trans fats. ADA recommends that a "reduced trans fat" claim is permitted when stated together with a "reduced saturated fat" claim. Allowing the claim "reduced trans fat" to be made for products that are also qualified to display a "reduced saturated fat" claim provides industry an incentive to remove or reduce trans fat from foods that contain trans fat without abandoning the saturated fat message. Therefore, ADA would support a claim permitting a "reduced trans fat" claim when the amount of trans fat contained in a product is reduced by 25 percent or more, and the amount of saturated fat is also reduced by 25 percent.

Because Americans generally consume significantly greater amounts of saturated

information about trans fat content will allow consumers to choose more healthful diets and help them to place individual food selections within the context of their total diet.

However, ADA believes the best scientific evidence suggests that consumers should focus first on total fat and saturated fat. And, because dietary intake of saturated fat is significantly higher than intake levels of trans fat, saturated fat presents a greater health risk to most Americans.

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Because Americans generally consume significantly greater amounts of saturated


fats relative to trans fats, ADA shares the concern of the agency that "use of a claim ["reduced trans fat"] could detract from educational messages that emphasize saturated fatty acids." ADA believes that a combined trans fat and saturated fat claim will ameliorate this concern while providing more complete and simplified information about atherosclerotic fats. In summary, ADA will support a rule that permits food manufacturers and marketers to make a reduced trans fat claim **when combined with** a reduced saturated fat claim.

Concluding Remarks

Continued consumer nutrition education efforts must also accompany our evolving knowledge of science as well as changes in the marketplace and labels. As new information emerges about the physiologic function of various fatty acids, even sophisticated consumers are likely to grow increasingly confused in the absence of clear consumer messages, including claims on food labeling. ADA members have the appropriate skills and training to provide nutrition guidance to consumers and remain committed to its mission to "promote optimal nutrition and well being for all people."

I am pleased to provide the above comments on behalf of the ADA and its members. If you have any questions or would like additional guidance on this issue, please contact Kate Gorton at (202) 775-8277.

Sincerely,
Jane V. White, PhD, RD, LD
President

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